Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PREETI LAL, JENNIFER L. HILLMAN, NEIL C. CORLEY, KARL J. GUEGLER, SUSAN K. SATHER, PURVI SHAH and MARIAH R. BAUGHN

Appeal No. 2002-0773
Application No. 09/002,485

HEARD: February 21, 2003

Before STONER, Chief Administrative Patent Judge, and WILLIAM F. SMITH and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 24-27 and 29-33. Claims 1, 15-18, 22, 23, 28, and 34-39 are also pending but have been withdrawn from consideration. See Paper No. 15, mailed December 5, 2000. The examiner also required Appellants to elect for examination a single amino acid and nucleotide sequence recited in the claims; Appellants elected the amino acid sequence of SEQ ID NO:25 and the nucleotide sequence of SEQ ID NO:102. See Paper No. 10, filed May 14, 1999.

The claims on appeal read as follows:

24. An isolated polynucleotide encoding a polypeptide having an amino acid sequence selected from the group consisting of [SEQ ID NO:1 through SEQ ID NO:77].

25. An isolated polynucleotide of claim 24 having a sequence selected from the group consisting of [SEQ ID NO:76 through SEQ ID NO:154].

26. A recombinant polynucleotide comprising a promoter sequence operably linked to a polynucleotide of claim 24.

27. A cell transformed with a recombinant polynucleotide of claim 26.

29. A method for producing a polypeptide having a sequence selected from the group consisting of [SEQ ID NO:1 through SEQ ID NO:77], the method comprising:

(a) culturing a cell under conditions suitable for expression of the polypeptide, wherein said cell is transformed with a recombinant polynucleotide, and said recombinant polynucleotide comprises a promoter sequence operably linked to a polynucleotide of claim 24; and

(b) recovering the polypeptide so expressed.

30. An isolated polynucleotide comprising a polynucleotide sequence selected from the group consisting of:
(a) a polynucleotide sequence selected from the group consisting of [SEQ ID NO:76 through SEQ ID NO:154];
(b) a polynucleotide sequence complementary to (a); and
(c) an RNA equivalent of (a)-(b).

31. An isolated polynucleotide comprising at least 60 contiguous nucleotides of a polynucleotide of claim 30.

32. A composition comprising a polynucleotide of claim 30 in conjunction with a suitable pharmaceutical excipient.

33. A microarray containing a fragment of at least one polynucleotide of claim 30, said fragment comprising at least 60 contiguous nucleotides of a polynucleotide of claim 30.

The examiner relies on the following references:

Rossi et al. (Rossi) "The Biology of Chemokines and their Receptors," Annu. Rev. Immunol, Vol. 18 pp. 217-242 (2000)

Vicari et al. (Vicari) "Teck : A Novel CC Chemokine Specifically Expressed by Thymic Dendritic Cells and Potentially Involved in T Cell Development," Immunity, Vol. 7, pp. 291-301 (1997)

Claims 24-27 and 29-33 stand rejected under 35 U.S.C. § 101 as lacking utility.

We affirm.

Background

A signal peptide, or signal sequence, is a short sequence of amino acids found at the amino terminus of some proteins that "directs, or targets, the protein from its ribosomal assembly site to a particular cellular or extracellular location." Specification, page 1. Signal sequences are commonly found in numerous families of proteins that might be of interest to researchers seeking new proteins with potential value as pharmaceuticals. See id.

The specification discloses cDNAs encoding a number of human signal peptide-containing proteins. The cDNAs were apparently identified by searching, in databases of partial cDNA sequences, for signal peptide-encoding DNA sequences, then stitching together a putatively full-length sequence by searching the databases for overlapping partial sequences. See, e.g., the specification's disclosure with respect to the elected polynucleotide sequence:

> Nucleic acids encoding the SIGP-25 of the present invention were first identified in Incyte Clone 1634813 from the cecal tissue cDNA library (COLNNOT19) using a computer search for amino acid sequence alignments. A consensus sequence, SEQ ID NO:102,

> was derived from Incyte Clones 1634813 (COLNNOT19), 2904583 (THYMNOT05), 1634813 (COLNNOT19) [sic], and 1310492 (COLNFET02), and shotgun sequence SAPA04436.
>
> In one embodiment, the invention encompasses a polypeptide comprising the amino acid sequence of SEQ ID NO:25. SIGP-25 is 150 amino acids in length and has one potential N-glycosylation site at N139; and five potential phosphorylation sites at T48, S118, S126, S135, and S136. SIGP-25 also has a potential signal peptide sequence encompassing residues M1-A23. SIGP-25 shares 28% identity with mouse beta chemokine, Exodus-2 (GI 2196924). The fragment of SEQ ID NO:102 from about nucleotide 175 to about nucleotide 235 is useful for hybridization. Northern analysis shows the expression of this sequence in gastrointestinal, developmental, hematopoietic, and immunological cDNA libraries. Approximately 50% of these libraries are associated with fetal development/cell proliferation and 25% with immune response.

Page 47. The specification provides no further characterization of the cDNA of SEQ ID NO:102 or the protein encoded thereby, although it states that "[c]hemokines are . . . small chemoattractant cytokines which are active in leukocyte trafficking. Initially, chemokines were isolated and purified from inflamed tissues. . . . Chemokines have been shown to be active in cell activation and migration, angiogenic and angiostatic activities, suppression of hematopoiesis, HIV infectivity, and promoting Th-1 (IL-2-, interferon γ-stimulated) cytokine release." Page 7.

The specification does not state which, if any, of these processes involves SIGP-25. The specification does, however, provide numerous suggestions regarding how one skilled in the art could use signal peptide-containing proteins generally. See, e.g., pages 90-91:

> The expression of the human signal peptide-containing proteins of the invention (SIGP) is closely associated with cell proliferation. Therefore, in cancers or immune response where SIGP is an activator, transcription factor, or enhancer, and is promoting cell

> proliferation, it is desirable to decrease the expression of SIGP. In conditions where SIGP is an inhibitor or suppressor and is controlling or decreasing cell proliferation, it is desirable to provide the protein or to increase expression of SIGP.
>
> In one embodiment, where SIGP is an inhibitor, SIGP or a fragment or derivative thereof may be administered to a subject to treat or prevent a cancer such as [any of a variety of cancer types and cancers of various tissues]. . . .
>
> . . .
>
> In a further embodiment where SIGP is promoting cell proliferation, antagonists which decrease the expression or activity of SIGP may be administered to a subject to treat or prevent a cancer such as [the same types of cancers and tissues listed as susceptible to treatment with SIGP itself]. . . .
>
> . . .
>
> In yet another embodiment where SIGP is promoting leukocyte activity or proliferation, antagonists which decrease the activity of SIGP may be administered to a subject to treat or prevent an immune response. Such responses include, but are not limited to, disorders such as AIDS . . ., atherosclerosis . . ., diabetes mellitus . . ., multiple sclerosis . . ., rheumatoid arthritis . . .; viral, bacterial, fungal, parasitic, protozoal, and helminthic infections; and trauma.

The specification also discloses that SIGP-encoding polynucleotides can be used in diagnosis. See page 100 ("The polynucleotides may be used to detect and quantitate gene expression in biopsied tissues in which expression of SIGP may be correlated with disease.") and page 102:

> Polynucleotide sequences encoding SIGP may be used for the diagnosis of a disorder associated with either increased or decreased expression of SIGP. Examples of such a disorder include, but are not limited to cancers such as [the now-familiar list of cancers of various types and tissues]; neuronal disorders such as . . . Alzheimer's disease, amnesia . . ., dementia, depression, Down's syndrome, . . ., schizophrenia, and Tourette's disorder; and immunological disorders such as AIDS . . ., atherosclerosis . . ., diabetes mellitus . . ., multiple sclerosis . . ., rheumatoid arthritis . . . and thyroiditis.

Finally, the specification discloses that SIGP-encoding cDNAs can be used in research. For example, they

> may be used as targets in a microarray. The microarray can be used to monitor the expression level of large numbers of genes simultaneously and to identify genetic variants, mutations, and polymorphisms. This information may be used to determine gene function, to understand the genetic basis of a disorder, to diagnose a disorder, and to develop and monitor the activities of therapeutic agents.
>
> . . .
>
> The microarray is preferably composed of a large number of unique single-stranded nucleic acid sequences, usually either synthetic antisense oligonucleotides or fragments of cDNAs. The oligonucleotides are preferably about 6 to 60 nucleotides in length, . . . most preferably about 20 to 25 nucleotides in length. It may be preferable to use oligonucleotides which are about 7 to 10 nucleotides in length. . . . Polynucleotides used in the microarray may be oligonucleotides specific to a gene or genes of interest. Oligonucleotides can also be specific to one or more unidentified cDNAs associated with a particular cell type or tissue type.

Pages 104-105. Alternatively, the polynucleotides "may be used to generate hybridization probes useful in mapping the naturally occurring genomic sequence." Page 106. "Correlation between the location of the gene encoding SIGP on a physical chromosome map and a specific disorder, or a predisposition to a specific disorder, may help define the region of DNA associated with that disorder." Pages 106-107. Finally, the signal peptide-containing protein "can be used for screening libraries of compounds in any of a variety of drug screening techniques. . . . The formation of binding complexes between SIGP and the agent being tested may be measured." Page 107.

Discussion

The claims are directed to polynucleotides encoding SIGP-25 or a fragment thereof (e.g., claims 30 and 31, respectively), a cell comprising the polynucleotide and a method of making the encoded protein (claims 27 and 29, respectively), a pharmaceutical composition comprising the polynucleotide (claim 32), and a microarray containing a fragment of the polynucleotide (claim 33). The sole issue on appeal is whether the claims are supported by a disclosure of utility sufficient to satisfy 35 U.S.C. § 101.[1]

We note at the outset that we are interpreting the claims as requiring the entire, specific amino acid or nucleotide sequences that are recited. For example, claim 24, which recites a "polynucleotide encoding a polypeptide having [the] amino acid sequence . . . of" SEQ ID NO:25 requires nucleotides encoding the entire sequence of SEQ ID NO:25 without substitutions, insertions, or deletions (although the open claim language permits additional sequences before and/or after the recited sequence). Likewise, claim 25, which recites a "polynucleotide of claim 24 having [the] sequence . . . of" SEQ ID NO:102, requires at least the entire, unaltered sequence of SEQ ID NO:102.

This interpretation of the claims is supported by their literal terms as well as by the prosecution history. The originally filed claims included claims to polynucleotides that hybridized under stringent conditions to a SIGP-encoding polynucleotide (claims 2 and 7) and polynucleotides having at least 90% identity

[1] While the examiner also rejected the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, that rejection is presented simply as a corollary of the finding of lack of utility. See the Examiner's Answer, pages 7-8. Therefore, our conclusion with respect to the § 101 issue will also apply to the § 112 issue.

to a SIGP-encoding polynucleotide (claim 5). These claims were rejected as anticipated by Wei (U.S. Patent 5,981,231), which the examiner characterized as disclosing a DNA that was 99.2% identical to SEQ ID NO:102 of the instant application. See Paper No. 12, mailed June 9, 2000. In response, Appellants cancelled claims 2-14 and replaced them with claims 24-39. See Paper No. 14, filed Sept. 11, 2000. Appellants stated that

> SEQ ID NO:25 of the instant application is patentably distinct from SEQ ID NO:2 of US Patent No. 5,981,231 in having Ala instead of Thr at position 23 and in having an additional Ala following the Gln at position 107. Consequently, SEQ ID NO:25 consists of 150 amino acids while SEQ ID NO:2 consists of 149 residues. Newly added Claims 24-39 (corresponding to original claims 2-14, now canceled) clarify the claimed invention and obviate the § 102(e) rejection.

Id., page 28. Thus, as the prosecution history makes clear, the language of the claims on appeal does not allow for any variation in the recited sequences,[2] even though the open claim language allows for inclusion of additional sequence(s) at the 3' or 5' end of the claimed polynucleotides.

The examiner rejected all of the elected claims for lack of utility. The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

---

[2] Thus, to the extent that the specification discusses SIGP "deletions," "derivatives," "substitutions", and "variants" (pages 24, 24-25, 29, and 29, respectively), the present claims do not encompass those embodiments.

The examiner found the specification's disclosure that the claimed products could be used in diagnosis or treatment of cancers and immunological disorders to be insufficient,

> because the specification fails to disclose any particular function or biological significance for the signal peptide-containing protein (SEQ ID NO:25) and the polynucleotide encoding it (SEQ ID NO:102). . . . The disclosed protein, whose cDNA has been isolated and is claimed, is said to have a potential function based upon its amino acid sequence similarity to other known proteins. After further research, a specific and substantial credible utility might be found for the claimed isolated compositions. This further characterization, however, is part of the act of invention and until it has been undertaken, Appellant's [sic] claimed invention is incomplete.

Examiner's Answer, page 5. The examiner added that "[t]here is absolutely no evidence of record or any line of reasoning that would support a conclusion that the claimed polynucleotide encoding a signal peptide-containing protein was, as of the filing date, useful 'in the diagnosis, treatment and prevention of cancer and immunological disorders' as stated [in] the specification." Id., page 6.

The examiner noted that the specification discloses that the protein encoded by the claimed polynucleotide has 28% sequence identity with a mouse chemokine, but concluded that "this is not a disclosure of how to use the protein (or the polynucleotide encoding it) because chemokines are a broad class of proteins which have divergent biological activity which cannot be predicted based on amino acid sequence information alone." Id., page 7.

Appellants argue that the claimed products have patentable utility because SIGP-25 has been identified as a putative chemokine and because all expressed human genes and polypeptides have utility sufficient to satisfy § 101. Appellants

argue, first, that SIGP-25 is a chemokine, and therefore "can be involved in immunological disorders. Furthermore, chemokines are involved in tumorigenesis and metastasis." Appeal Brief, page 4.[3] Appellants also argue that SIGP-25 is 98% identical to "human TECK (thymus-expressed chemokine), a chemokine specifically expressed by thymic dendritic cells and potentially involved in T-cell development." Id. Appellants conclude that "the practi[ti]oner would not doubt that SEQ ID NO:25 is a human lymphocyte-specific chemokine and, as such molecules, have [sic] numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease." Id., page 5.

In addition, Appellants argue that the "claimed invention has numerous other uses, including: stimulating lymphoid development, controlling lymphoid migration, stimulating lymphocytes to boost immune response, attracting or repelling lymphocytes to/from sites of infection, inflammation, or tissue damage, and repelling lymphocytes from tissues of the central nervous system following trauma." Id., page 14.

We do not agree with Appellants that the claimed polynucleotides have utility because the encoded protein has been identified as a putative chemokine. Again, all that Appellants' specification discloses regarding SIGP-25 specifically is that it has 28% sequence identity to a protein identified as "mouse beta chemokine, Exodus-2 (GI 2196924)." No further information is provided regarding the activity or function of either the protein encoded by the claimed polynucleotides or the mouse chemokine with which it has 28% sequence identity.

[3] "Appeal Brief" refers to the Revised Brief on Appeal (Paper No. 21, filed August 27, 2001).

The evidence of record shows that chemokines have widely varying activities in vivo. See, e.g., the instant specification, which discloses that "[c]hemokines have been shown to be active in cell activation and migration, angiogenic and angiostatic activities, suppression of hematopoiesis, HIV infectivity, and promoting Th-1 (IL-2-, interferon γ-stimulated) cytokine release." Page 7. See also the reference by Rossi (cited by Appellants):[4] Figure 1 shows that chemokines can be involved in lymphoid trafficking, wound healing, Th1/Th2 development, angiogenesis/angiostasis, metastasis, cell recruitment, inflammation, or lymphoid organ development. The specification provides no basis for concluding which, if any, of the activities of the various known chemokines is shared by SIGP-25.

Thus, although the evidence supports Appellants' position that some chemokines are involved in immunological disorders, and some chemokines are involved in tumorigenesis and metastasis, there is no evidence that all chemokines are involved in any of these processes, nor that SIGP-25 is involved in any of them, nor that a person of skill in the art would have appreciated that the identification of SIGP-25 as a chemokine, without more, would have suggested any specific patentable utility. We therefore reject Appellants' argument that § 101 is satisfied by SIGP-25's sequence similarity to the known mouse chemokine Exodus-2.

---

[4] Rossi et al., "The biology of chemokines and their receptors," Annu. Rev. Immunol., Vol. 18, pp. 217-242 (2000). Rossi is not prior art with respect to the instant claims, and there is no basis for concluding that it reflects the state of the art as of the application's filing date. We cite it only as evidence supporting the specification's statement that chemokines were known to participate in a wide variety of cellular processes.

Appellants also argue that SIGP-25 is 98% identical to a human chemokine known as TECK, and that a person skilled in the art would therefore conclude that it is "a human lymphocyte-specific chemokine . . . hav[ing] numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease." Appeal Brief, pages 4-5.

This argument is also unpersuasive. First, the instant specification does not disclose that SIGP-25 is a thymus-expressed chemokine, nor does it disclose what particular utility would be expected for a chemokine that shows a pattern of thymus-specific expression. Appellants cite a reference by Vicari[5] as the basis for their assertion that SIGP-25 is 98% identical to human TECK. Vicari states that the data disclosed therein

> strongly suggest that TECK is a novel chemokine specifically expressed by activated lymphoid-derived dendritic cells.
>
> Through their function of antigen presentation, dendritic cells play major roles in the establishment of tolerance and in the initiation of an antigen-specific immune response. The use of purified dendritic cells has been recently proposed in different therapeutic protocols. . . . The discovery of factors with a regulated expression in dendritic cells such as the novel CC chemokine TECK will improve our knowledge of the biology of dendritic cells and lead to the design of relevant in vivo applications.

Page 298.

We do not agree with Appellants that Vicari can be relied on to supplement the instant specification, in order to meet the utility requirement of § 101. First, the specification does not disclose or even suggest that SIGP-25 is expressed specifically in the thymus. While a specification need not disclose what is well

known in the art, that rule does not excuse an applicant from providing a complete disclosure. See Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): "It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." The same is true of utility.

In addition, neither the specification nor Vicari suggest that a pattern of thymus-specific expression would have been understood by those skilled in the art to imply that the chemokine was useful for any particular purpose. Vicari speculates that the discovery of TECK would "lead to the design of relevant in vivo applications," but provides no hint what those applications would be.

Appellants argue in their Appeal Brief that, as "a human lymphocyte-specific chemokine," SIGP-25 would "have numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease." Page 5. This position is not supported by the specification. The specification does not disclose that SIGP-25 in particular, or signal peptide-containing proteins in general, are useful for toxicology testing. Nor does the specification disclose what drug(s) SIGP-25 would be useful in developing, or what disease(s) it would be useful in diagnosing. The specification provides no basis for concluding that SIGP-25 is associated with any specific disease.

Finally, Appellants argue that SIGP-25 would be useful in a number of applications relating to lymphocytes. See the Appeal Brief, page 14 ("stimulating lymphoid development, controlling lymphoid migration, stimulating lymphocytes

---

[5] Vicari et al., "TECK: A novel CC chemokine specifically expressed by thymic dendritic cells and

to boost immune response, attracting or repelling lymphocytes to/from sites of infection, inflammation, or tissue damage, and repelling lymphocytes from tissues of the central nervous system following trauma.").

Appellants have pointed to no evidence in the record supporting their assertion that SIGP-25 would have been recognized as useful in any of the recited processes. "Attorney's argument in a brief cannot take the place of evidence." In re Pearson, 494 F.2d 1399, 1405, 181 USPQ 641, 646 (CCPA 1974). The uses asserted on page 14 of the brief, being unsupported by evidence, cannot be relied on to satisfy § 101.

In a second line of reasoning, Appellants argue that all expressed human genes have utility. See, e.g., the Appeal Brief, pages 7-9. Appellants reason that the technique of expression profiling, in which the expression of numerous genes is compared in two or more samples, is used in research relating to toxicology testing, drug development, and disease diagnosis. See id., page 7. "Genes or gene fragments known to be expressed, such as the invention at issue, are tools essential to any technology that uses expression profiling." Id. "The more genes that are available for use in toxicology testing, the more powerful the technique." Id., page 8. "[T]here is no expressed gene which is irrelevant to screening for toxicological effects, and all expressed genes have a utility for toxicological screening. This is true for both polynucleotides and polypeptides encoded by them." Id.

---

potentially involved in T cell development," Immunity, Vol. 7, pp. 291-301 (1997). Vicari was published before the filing date of the instant application.

According to Appellants, "[as] used in toxicology testing, drug discovery, and disease diagnosis, the claimed invention has a beneficial use in research other than studying the claimed invention or its protein products. It is a tool, rather than an object, of research." Id., page 10. Appellants argue that this distinguishes the instant case from cases like Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), and In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967), where "the only known use for the claimed invention [was] to be an **object** of further study." Appeal Brief, page 9 (emphasis in original).

Appellants assert that "[t]he claimed invention could be used, for example, in a toxicology test to determine whether a drug or toxin causes any change in the expression of lymphocyte-specific chemokines. Similarly, the claimed invention could be used to determine whether a specific medical condition, such as cancer, affects the expression of lymphocyte-specific chemokines and, perhaps in conjunction with other information, serve as a marker for or to assess the stage of a particular disease or condition." Appeal Brief, page 11.

Or, according to Appellants, "the claimed polypeptide and/or polynucleotide sequences could be used in toxicology testing and diagnosis . . . : it could serve, for example, as a marker of a toxic response, or, alternatively, if levels of the claimed polypeptide or polynucleotide remain unchanged during a toxic response, as a control in toxicology testing. Diagnosis of disease . . . can be achieved using arrays of numerous identifiable, expressed DNA sequences . . . notwithstanding lack of any knowledge of the specific functions of the proteins they encode." Id., pages 11-12.

Appellants argue that § 101 is satisfied by utilities that apply equally to all expressed human genes and proteins; the utility need not be "particular" to the claimed invention. See the Appeal Brief, pages 12-15 and 16-18. "Practical real-world uses are not limited to uses that are unique to an invention." Id., page 17. According to Appellants, "**all** isolated and purified naturally occurring polynucleotide and polypeptide sequences which are expressible . . . can be and **are** used in a real-world context as tools for toxicological testing, e.g., for drug discovery purposes." Id., page 14 (emphasis in original).

Thus, Appellants argue, the claimed products have sufficient utility to satisfy § 101. Appellants distinguish cases like Kirk on the basis that "[w]here courts have found utility to be too 'general,' it has been in those cases in which the asserted utility in the patent disclosure was not a practical use that conferred a specific benefit. That is, a person of ordinary skill in the art would have been left to guess as to how to benefit at all from the invention." Id., page 17.

We cannot agree with Appellants' position. First, the specification's only disclosure regarding microarrays is found on pages 104-105. That disclosure states only that microarrays "can be used to monitor the expression level of large numbers of genes simultaneously and to identify genetic variants, mutations, and polymorphisms. This information may be used to determine gene function, to understand the genetic basis of a disorder, to diagnose a disorder, and to develop and monitor the activities of therapeutic agents." Page 104. The specification does not disclose the use of microarrays for toxicology testing. In addition, the specification does not disclose what disorder(s) could be diagnosed

using a microarray comprising the claimed polynucleotides, nor what to do with any "therapeutic agents" developed using such a microarray.

Appellants argue that the use of microarrays in such processes is "well-established" and therefore need not be expressly disclosed in the specification. See the Appeal Brief, pages 7-10. However, the references that Appellants cite to show the "well-established" nature of these utilities were all published after the filing date of the instant application. Thus, none of Appellants' references provide evidence that, as of the date the present application was filed, those of skill in the art would have recognized the asserted utilities as well-established.

In addition, even assuming arguendo that the use of microarrays to monitor gene expression in research related to toxicology testing, drug development, and disease diagnosis was well-established as the application's filing date, we do not find Appellants' argument persuasive. We find that merely using the claimed polynucleotides as a component of a microarray would not satisfy § 101's utility requirement, as it has been interpreted by the courts.[6]

The seminal decision interpreting the utility requirement of § 101 is Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). At issue in Brenner was a claim to "a chemical process which yields an already known product whose utility—other than as a possible object of scientific inquiry—ha[d] not yet been evidenced." Id. at 529, 148 USPQ at 693. The Patent Office had rejected the claimed process for lack of utility, on the basis that the product produced by

[6] The examiner based her analysis largely on the recently issued Utility Examination Guidelines. See 66 Fed. Reg. 1092 (Jan. 5, 2001). The Guidelines expressly do not have the force and effect of law, see id. at 1098, and our analysis is based instead on controlling precedent. We note,

the claimed process had not been shown to be useful. See id. at 521-22, 148 USPQ at 690. On appeal, the Court of Customs and Patent Appeals reversed, on the basis that "where a claimed process produces a known product it is not necessary to show utility for the product." Id. at 522, 148 USPQ at 691.

The Brenner Court noted that although § 101 requires that an invention be "useful," that "simple, everyday word can be pregnant with ambiguity when applied to the facts of life." Id. at 529, 148 USPQ at 693. Thus,

> [it] is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the "new and useful" phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man's grasp and where little or nothing is wholly beyond the pale of "utility"—if that word is given its broadest reach.

Id. at 530, 148 USPQ at 694.[7]

The Court, finding "no specific assistance in the legislative materials underlying § 101," based its analysis on "the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other." Id. at 532, 148 USPQ at 695. The Court concluded that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification

---

however, that our conclusion is entirely consistent with the conclusion reached by the examiner in applying the Utility Examination Guidelines.

[7] The invention at issue in Brenner was a process, but the Court expressly noted that its holding "would apply equally to the patenting of the product produced by the process." Id. at 535, 148 USPQ at 695-96.

for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

The Court considered and rejected the applicant's argument that attenuating the requirement of utility "would encourage inventors of new processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge." The Court noted that, while there is value to encouraging disclosure, "a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development." Id. at 534, 148 USPQ at 695.

The Court took pains to note that it did not "mean to disparage the importance of contributions to the fund of scientific information short of the invention of something 'useful,'" and that it was not "blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public." Id. at 535-36, 148 USPQ at 696. Those considerations did not sway the Court, however, because "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id.

Subsequent decisions of the CCPA and the Court of Appeals for the Federal Circuit have added further layers of judicial gloss to the meaning of § 101's utility requirement. The first opinion of the CCPA applying Brenner was In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties and to be of value "in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice." Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly "show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests." Id. at 939, 153 USPQ at 51.

The court held that "nebulous expressions [like] 'biological activity' or 'biological properties'" did not adequately convey how to use the claimed compounds. Id. at 941, 153 USPQ at 52. Nor did the applicants' affidavit help their case: "the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know 'how to use' the compounds to find out in the first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are." Id. at 942, 153 USPQ at 53.

The Kirk court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by Brenner. "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or

arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court" in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at 55.

More recently, in In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993), the Federal Circuit considered the degree of specificity required to show utility for a claim to polypropylene. The U.S. application on appeal in Ziegler claimed priority to a German application filed in 1954. "In the German application, Ziegler disclosed only that solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was 'plastic-like.'" Id. at 1203, 26 USPQ2d at 1605. "Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility." Id. The court held that the German application did not satisfy the requirements of § 101 and therefore could not be relied on to overcome a rejection based on an intervening reference. See id., 26 USPQ2d at 1606. "[At] best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there." Id., 26 USPQ2d at 1605.

On the other hand, the CCPA reversed a rejection for lack of utility in In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). The applicant in Jolles claimed pharmaceutical compositions that were disclosed to be useful in treating acute myeloblastic leukemia. See id. at 1323, 206 USPQ at 886. The active ingredients in the compositions were closely related to daunorubicin and

doxorubicin, both of which were "well recognized in the art as valuable for use in cancer chemotherapy." Id., 206 USPQ at 887. The applicant also submitted declaratory evidence showing that eight of the claimed compositions were effective in treating tumors in a mouse model, and one was effective in treating humans. See id. at 1323-24, 206 USPQ at 887-88. The court noted that the data derived from the mouse model were "relevant to the treatment of humans and [were] not to be disregarded," id. at 1327, 206 USPQ at 890, and held that the evidence was sufficient to support the asserted therapeutic utility. See id. at 1327-28, 206 USPQ at 891.

The Federal Circuit held in Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), that in vivo testing (as in Jolles) was not necessarily required to show utility in the pharmaceutical context. The Cross court stated that "[it] is axiomatic that an invention cannot be considered 'useful,' in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious." Id. at 1044, 224 USPQ at 742 (citing Brenner v. Manson). The court "perceive[d] no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question." Id. at 1051, 224 USPQ at 748. Successful in vitro testing could provide an immediate benefit to the public, by "marshal[ling] resources and direct[ing] the expenditure of effort to further in vivo testing of the most potent compounds . . ., analogous to the benefit provided by the showing of an in vivo utility." Id. On the facts of that case – successful in vitro testing

supplemented by similar in vitro and in vivo activities of structurally similar compounds – the court held that in vitro activity was sufficient to meet the requirements of § 101. See id.

The Federal Circuit confirmed in In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), that human testing is not necessary to establish utility for a method of treatment. The invention claimed in Brana was a group of compounds disclosed to have antitumor activity. See id. at 1562, 34 USPQ2d at 1437-38. The specification disclosed that the claimed compounds had higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of in vivo activity against tumors in a mouse model. See id., 34 USPQ2d at 1438. The court held that these data were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. See id. at 1567, 34 USPQ2d at 1442.

Several lessons can be drawn from Brenner and its progeny. First, § 101's requirement that an invention be "useful" is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every "use" that can be asserted will be sufficient to satisfy § 101. For example, the steroid compound at issue in Brenner was useful as a possible object of scientific inquiry, and the polypropylene claimed in Ziegler was useful for pressing into a flexible film, yet both lacked sufficient utility to satisfy § 101. See Brenner, 383 U.S. at 529, 148 USPQ at 696; Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

Rather than setting a de minimis standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (Jolles, 628 F.2d at 1327-28, 206 USPQ at 891); by evidence showing successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds (Cross, 753 F.2d at 1051, 224 USPQ at 748); and by evidence showing in vivo antitumor activity in mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana, 51 F.3d at 1567, 34 USPQ2d at 1442).

By contrast, Brenner's standard has been interpreted to mean that "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" would not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Likewise, a disclosure of a "plastic-like" polypropylene capable of being pressed into a flexible film was held to show that the applicant was "at best . . . on the way to discovering a practical utility for polypropylene at the time of the filing," but not yet there. Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

We find that the asserted utility of the claimed polynucleotides—as a component of a microarray for monitoring gene expression—does not satisfy the utility requirement of § 101. Such a use does not provide a specific benefit in currently available form.

We accept for argument's sake that a person skilled in the art could attach one of the claimed polynucleotides (or a part of it) to a solid substrate, in combination with other polynucleotides, to form a microarray. We can also accept, for argument's sake, that such a microarray could be used to monitor changes in expression of the gene that encodes SIGP-25. However, the specification provides no guidance to allow a skilled artisan to use data relating to SIGP-25 expression in any practical way. The specification simply provides no guidance regarding what the SIGP-25-specific information derived from a microarray would mean.

Assume, for example, that a fragment of SEQ ID NO:102 was attached to a microarray and the researcher observed that SIGP-25 expression was increased when a cell was treated with a particular agent. The specification provides no basis on which a skilled worker would be able to determine whether that result is meaningful. Maybe the meaning in a change in SIGP-25 expression would depend on other factors, but again the specification provides no hint what other factors might be important. Would it depend on what agent is used, what cell type is used, the behavior of other genes (if so, which genes and what behavior is significant), the degree of increase? The specification simply provides no guidance as to how to interpret the results that might be seen using SIGP-25 in microarray-based gene expression assay.

In effect, Appellants' position is that the claimed polynucleotides are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental results might mean. We do not

agree that such a disclosure provides a "specific benefit in currently available form." Rather, the instant case seems analogous to Brenner. In Brenner, the applicant claimed a method of making a compound but disclosed no utility for the compound. 383 U.S. at 529, 148 USPQ at 693. The Court held that a process lacks utility if it produces a product that lacks utility. Id. at 534, 148 USPQ at 695. Here, the applicants claim a product asserted to be useful in a method of generating gene-expression data, but the specification does not disclose how to interpret those data. Just as the process claimed in Brenner lacked utility because the specification did not disclose how to use the end-product, the product claims here lack utility, based on their use in microarrays, because the specification does not disclose how to use the SIGP-25-specific gene expression data generated by a microarray.

Appellants argue that the use of polynucleotides in microarrays is a patentable utility, even though they assert that it applies to all expressed genes, because there is no legal requirement that an invention's utility be "unique" to the invention. Rather, Appellants argue, an invention can be a member of a class, where all the members of the class share a common utility.

First, Appellants' characterization of the Office's position is somewhat misleading. Appellants have never been asked to identify a utility that is unique, i.e., not shared by any other compounds or compositions. Rather, Appellants have been required to identify a utility that is specific to the invention claimed, as opposed to one that would apply regardless of the specific properties of the claimed invention. See, e.g., Brenner, 383 U.S. at 534, 148 USPQ at 695 (An

invention does not have utility sufficient to satisfy § 101 until it is "refined and developed" to the point of providing a specific benefit in currently available form.).

An invention certainly can have a utility that is shared by other compounds or compositions. Take, for example, an application that claims ibuprofen and discloses that it is useful as an analgesic. No one would argue that a claim to ibuprofen lacks utility simply because aspirin and acetaminophen are also useful as analgesics. On the other hand, not every utility will satisfy § 101, even if the utility is shared by a class of inventions. Assume that the above-described application did not disclose that ibuprofen was an analgesic but only disclosed that it is useful because it can be used to fill a jar, which would then be useful as a paperweight. There would be little doubt that this disclosed utility would not satisfy § 101, even though the utility is shared by a large class of inventions, viz., those whose physical embodiments have mass. So while a utility need not be unique to a claimed invention, it must nonetheless be specific, and in currently available form, in order to satisfy § 101.

Here, Appellants assert that any expressed human gene or protein can be incorporated into a microarray, and that the microarray can then be used to monitor changes in expression of the genes represented therein. However, any observed results of changed expression of the SIGP-25-encoding gene would have no meaning without additional knowledge of what a change in expression of SIGP-25 means. The specification in effect discloses that the claimed products can be put on microarrays, and those of skill in the art will figure out what to do

with them. This utility is not substantial; it does not provide a specific benefit in currently available form.

Appellants' position may be that a microarray has utility, and a microarray is made up of thousands of genes or gene fragments; therefore, since the genes collectively provide the data generated by the microarray, each one of the genes represented in the microarray has utility. We decline to attenuate the utility requirement to this degree.

Assuming arguendo that a generic microarray—one comprising thousands of uncharacterized or semi-characterized gene fragments—would provide a useful tool for, e.g., drug discovery, it does not follow that each one of the genes represented in the microarray individually has patentable utility. Although each gene in the microarray contributes to the data generated by the microarray overall, the contribution of a single gene—its data point—is only a tiny contribution to the overall picture.

The Brenner Court held that § 101 sets more than a de minimis standard for utility. Therefore, the patentable utility of a microarray, for example, does not necessarily mean that each tiny component of the microarray also has patentable utility. A patentable utility divided by a thousand does not necessarily equal a thousand patentable utilities. Each claimed invention must be shown to meet § 101's utility requirement in order to be patentable; it must provide a specific benefit in currently available form. Providing a single data point among thousands or millions, even if the thousands or millions of data points collectively are useful, does not meet this standard.

The Supreme Court noted that the patent system contemplates a basic quid pro quo: in exchange for the legal right to exclude others from his invention for a period of time, an inventor discloses his invention to the public. See Brenner, 383 U.S. at 534, 148 USPQ at 695. The Brenner Court held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility – a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the applicant has not met his side of the bargain, and has not provided a disclosure sufficient to justify a grant of the right to exclude others. See id.

In this case, Appellants seek the right to exclude others from using the claimed invention, which includes

- the DNA of SEQ ID NO:102 (claim 25),
- its complement (claim 30),
- any fragment 60 or more nucleotides long (claim 31),
- all other degenerate DNAs encoding SEQ ID NO:25 (claim 24),
- recombinant vectors comprising such DNAs (claim 26),
- host cells and methods of making the encoded protein (claims 27 and 29),
- pharmaceutical compositions comprising SEQ ID NO:102 or its complement (claim 32), and
- a microarray comprising a fragment of SEQ ID NO:102 or its complement (claim 33).

In return for the right to exclude others from using all of these products, Appellants contend that it is enough for them to simply disclose the structure of the claimed polynucleotides, with no disclosure of the encoded protein whatever. See the Appeal Brief, page 11 ("In fact, the claimed . . . polynucleotide sequences could be used in toxicology testing and diagnosis without any

knowledge (although this is not the case here) of the protein for which it codes."). We do not agree that such a disclosure satisfies § 101. The basic quid pro quo of the patent system, as interpreted by the Brenner Court, is the grant of a valuable legal right in exchange for a meaningful disclosure of the claimed invention. Appellants' bare-bones disclosure in this case does not entitle them to the legal right they claim.

In addition, it is noteworthy that only one of the claims on appeal is directed to the microarray on which Appellants base most of their broad assertions of utility. In addition to the microarray, Appellants also claim a host cell containing a polynucleotide encoding SEQ ID NO:25 under control of a promoter, a method of making the protein of SEQ ID NO:25, and a composition comprising SEQ ID NO:102 and a "pharmaceutical excipient." Neither the method nor either product has any apparent use in a microarray gene-expression assay.

It would appear, therefore, that Appellants are using the asserted microarray utility as a stalking horse, to provide a utility that can be asserted for any isolated cDNA, regardless of how little is known about it, which (they hope) will nonetheless serve as a basis for patent protection of all related products and methods and secure for Appellants any value that might become apparent in the future, after they or others have further characterized the claimed products. It was precisely this type of result that the Brenner Court sought to avoid by requiring disclosure of a substantial utility to satisfy § 101. See 148 U.S. at 535-36, 148 USPQ at 696: [The Court was not] "blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public.

But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id.

The polynucleotides of the instant claims may indeed prove to be very useful (and valuable), after the in vivo role of the encoded protein is discovered. The work required to confer value on SIGP-25, however, remains to be done. The instant specification's SIGP-25-specific disclosure does not justify a grant of patent rights. See Brenner, 383 U.S. at 534, 148 USPQ at 695: "[A] process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development." We consider the Brenner Court's concern about the "power to block off whole areas of scientific development" equally applicable here.

Finally, in addition to being contrary to controlling case law, the per se rule that Appellants seek—that any expressed human gene has utility because it can be used in a microarray—would disserve the patent system. In the first place, it is unclear what, if anything, limits the compounds subject to Appellants' proposed rule. Appellants have asserted that this rationale would apply to wholly uncharacterized nucleotide sequences. See the Appeal Brief, pages 11-12. It is also apparent that it applies not only to intact genes, but to fragments of them as

small as six nucleotides long. See the specification, page 104 ("The microarray is preferably composed of a large number of unique single-stranded nucleic acid sequences. . . . The oligonucleotides are preferably about 6 to 60 nucleotides in length.").

Nor can the rationale be confined to expressed human genes. We can take judicial notice of the fact that other organisms are of interest for many different reasons, such that gene expression assays could conceivably be used in their research. For example, some organisms are of interest to researchers because they have been historically well-studied (e.g., yeast, Arabidopsis, C. elegans, Drosophila). Other organisms are of interest because they are used as animal models for testing pharmaceuticals (e.g., mice, chimpanzees, rhesus monkeys, rabbits), or because they are commercially valuable (e.g., pigs, cows, corn, rice, tomatoes), or because they are pests (e.g., fungi such as Fusarium, common weeds like ragweed, insects such as corn borers, nonnative invaders such as zebra mussels, etc.), or because they're pathogens (e.g., Candida, various bacteria, tapeworms, etc.). Under Appellants' proposed rule, every six base pair-long fragment of any gene of any of these organisms—and probably most other organisms—would be found to have patentable utility because it could be attached to a chip and used in "research" to see what happens to expression of that gene under various conditions.

As if that were not enough, according to Appellants, the microarray technique is also applicable to proteins. See the Appeal Brief, page 8 ("[T]here is no expressed gene which is irrelevant to screening for toxicological effects, and

all expressed genes have a utility for toxicological screening. This is true for both polynucleotides and polypeptides encoded by them."). The brief provides no further detail regarding polypeptide microarrays but presumably they are related to the "drug screening techniques" discussed in the specification. See page 107 ("SIGP . . . or oligopeptide fragments thereof can be used for screening libraries of compounds in any of a variety of drug screening techniques. The fragment employed in such screening may be free in solution [or] affixed to a solid support. . . . The formation of binding complexes between SIGP and the agent being tested may be measured.").

This reasoning—that fragments of proteins can be fixed to a surface and used to screen compounds for binding to other compounds—cannot logically be confined to the proteins themselves. By extension, the compounds of interest could also be affixed to a surface (i.e., a microarray) and exposed to cellular proteins, in order to assay for binding in the same manner. It would seem, therefore, that Appellants' proposed rule would require a finding of utility for any compound which might bind or be bound by any other compound of physiological significance.

It is apparent, therefore, that Appellants' proposed rule would vitiate the statutory utility requirement for most chemical compounds. If Appellants' reasoning were adopted, it would result in a per se rule that all chemical compounds have utility because each one can be used to do research on others.

Appellants' reasoning would also vitiate the enablement requirement, since "[t]he enablement requirement is met if the description enables any mode

of making and using the invention." Johns Hopkins Univ. v. CellPro Inc., 152 F.3d 1342, 1361, 47 USPQ2d 1705, 1714 (Fed. Cir. 1998) (quoting Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991)). If we were to agree with Appellants that any expressed gene, any six base pair-long fragment thereof, and any expressed protein is useful in a microarray, then we would also have to hold that the specification has taught those skilled in the art one mode of using the invention. Thus, Appellants' rule of per se utility would also require a corresponding rule of per se enablement.

What limit then would remain on patenting of genes and proteins (and potentially any other bioactive compound)? It would seem that under Appellants' rule, a compound would be patentable if it was adequately described in the specification and was not disclosed or suggested in the prior art. This standard, however, is not the one set by Congress, which requires that a patentable invention also be useful and fully enabled, nor is it the standard that has been consistently applied by the courts.

Summary

The patent system is based on a balancing of interests. "Patents . . . are meant to encourage invention by rewarding the inventor with the right, limited to a term of years fixed by the patent, to exclude others from the use of his invention. . . . But in rewarding useful invention, the 'rights and welfare of the community must be fairly dealt with and effectually guarded.' Kendall v. Winsor, 21 How. 322, 329 (1859). To that end the prerequisites to obtaining a patent are strictly observed. . . . To begin with, a genuine 'invention' or 'discovery' must be

demonstrated 'lest in the constant demand for new appliances the heavy hand of tribute be laid on each slight technological advance in an art.'" Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 230, 140 USPQ 524, 527 (1964).

The basic quid pro quo of the patent system requires disclosure of an invention having substantial utility. Appellants' disclosure in this case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101.

The examiner's rejections under 35 U.S.C. §§ 101 and 112, first paragraph, are affirmed. However, since our basis for affirming the rejections differs somewhat from the examiner's, we designate the affirmance as a new ground of rejection under 37 CFR § 1.196(b) in order to provide Appellants with a fair opportunity to respond. See In re Kronig, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426-27 (CCPA 1976).

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED; 37 CFR § 1.196(b)

Bruce H. Stoner, Jr., Chief)
Administrative Patent Judge)
)
)
William F. Smith) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
Eric Grimes)
Administrative Patent Judge)

Incyte Genomics, Inc.
3160 Porter Dive
Palo Alto, California 94304

EG/dym